

aged 39 days (17 days for oncology and 14 days for orphan drugs). Across the EU5, Germany was fastest while Italy was slowest (16 vs. 66 weeks). Other factors considered included: UK reimbursement decisions by SMC and NICE often lengthened time to access; Germany: Time to market has increased by ~8 weeks since the 2011 introduction of AMNOG; Italy and France have special license programs which can shorten time to market for products addressing unique needs or populations; and In Spain commercialization of orphan and oncology drugs takes longer than general medications. **CONCLUSIONS:** Average time to market in the US vs. EU5 countries is considerably different. In the EU5, the German and UK launch on average were within 4 to 6 months of authorization; Italy was greater than a year. Launch times for orphan and oncology drugs also differ based on priorities set within health systems. Differences in country and product type have led to different market access timelines and regulatory changes will only increase these disparities.

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EFFECTS OF DRUG COST SHARING POLICY ON THE DRUG USE, FINANCIAL RISKS AND MORAL HAZARD FOR THE HEALTH INSURANCE BENEFICIARIES

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OBJECTIVES: To describe policies of drug cost sharing in health insurance schemes and how the authors have assessed the effects where available. **METHODS:** A systematic review was conducted in 2009 and updated in 2013. **RESULTS:** Totally 28 studies were included. 1) Some insurance schemes introduced a new drug cost sharing program, the increase rates of total number of prescriptions were smaller compared with the non cost-sharing group; At the same time, prescription drug cost sharing also decreased use of essential drugs or adherence to medications which induced adverse effects on vulnerable population such as the poor, the elderly and patients with chronic diseases. Average prescription cost increase rate was lower in the cost sharing group than the non cost-sharing group. 2) For Different Tiers of Prescription Copayment System, there were some positive effects showing that the consumption of generic drugs increased in both single-tiered and three-tiered groups, especially higher proportion in the three-tiered system. Higher levels of prescription drug cost sharing actually decrease inappropriate drug use with a relatively inelastic price elasticity of demand. For the patients with chronic diseases such as heart failure or diabetes, lower adherence of medication followed by higher copayment would increase risk of hospitalization. Different levels of copayment could control moral hazard of the patients with decreased rates of switching to a relatively more expensive drug and an increased rate of switching to drugs of equal or lesser cost. 3) Increasing cost sharing level was followed by decreasing the utilization of prescription drugs and increasing in out of pocket especially for the vulnerable population. **CONCLUSIONS:** To increase or decrease the level of cost sharing could change the beneficiaries' behavior, the vulnerable population were more sensitive than the general. Different levels of cost sharing method seem as one of the successful tools to control moral hazard.

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AN ANALYSIS OF THE DRIVERS OF PRICING PREMIUMS GRANTED TO INNOVATIVE PRODUCTS IN JAPAN

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OBJECTIVES: The objective of this study was to identify key value drivers to achieve pricing premiums through the similar efficacy comparator pricing method for innovative products in Japan. **METHODS:** We analysed all products that were priced by the Central Social Insurance Medical Council (Chuiyao) using the similar efficacy comparator pricing method (I) from January 2010 to March 2014. Where relevant, the pricing premium and premium criteria met within each category were analysed in detail. **RESULTS:** Of 102 products assessed, 36 products (35%) were granted pricing premiums, which ranged from 5-50%. The most common premium category was utility (69%), followed by paediatric use (19%) and marketability (17%). Four products fell into two categories and were granted both pricing premiums. Of the seven orphan drugs assessed, six gained a 10% marketability (I) premium, while one achieved marketability (II) with only a 5% premium, as the orphan indication was not its main indication. Paediatric-use premiums ranged from 5-10%, with higher premiums dependent on unmet need and availability of similar therapies. 5-15% utility (II) premiums were achieved by products with improved MOA, efficacy, safety or therapeutic method. Only two products, fingolimod and telaprevir, were designated as utility (I) innovations, which qualified them for pricing premiums of 35-60%. Fingolimod was the first oral therapy approved to treat relapsing forms of multiple sclerosis. Its novel MOA, improved administration and efficacy, as well as an orphan indication, secured fingolimod a 50% pricing premium. Similarly, telaprevir was also valued by Chuiyao for its novel MOA and significant clinical improvement over the standard of care, resulting in a 40% pricing premium. **CONCLUSIONS:** Clinical benefit and unmet need are the main value drivers for premium pricing in Japan. To achieve >20% pricing premium, a product needs to meet at least two utility premium criteria to be categorized to utility (I).

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CHINA CRITICAL ILLNESS INSURANCE POLICY - THE RECENT DEVELOPMENTS AND PROSPECTS

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OBJECTIVES: China has a complex system to provide basic medical insurance (BMI) for over 95% population. However 35% of the total medical expense is out-of-pocket. To relieve people's burden, China implemented critical illness insurance from 2012. Critical illness insurance is based on BMI and aims to provide further protection for urban and rural unemployed residents. The article aims to summarize the plans of critical illness insurance from 24 provinces, to conclude the developments and prospects. **METHODS:** The 24 plans were published from October 2012 to December 2013. The participants of the insurance are urban and (or) rural residents. All plans

determined that the payment amount will be segmented calculated. Besides, commercial companies are responsible to provide insurance. Thus the article summarizes and compares the financing level, deductible and cap lines. **RESULTS:** 18 provinces determined the financing level: 11 provinces were from 10 CNY to 60 CNY per capita annually; the rest equaled 5% to 10% of BMI premium. 22 provinces determined deductible: 15 provinces calculated deductible based on urban per capita disposable income (or rural per capita net income). 7 provinces determined cap line: 4 provinces were from 200 000 CNY to 400 000 CNY and the rest were no cap. **CONCLUSIONS:** 1. In all related provinces, the financing level is relatively low, while segmented calculation and the cap line lead to high payment. The main challenge is how to balance the income and expenditure of the insurance. 2. Since the central government did not define what critical illness insurance can reimburse, some provincial governments strictly control the range. In some other provincial governments, like Anhui, the range of the insurance is too wide. However, considering the insurer is commercial companies, the gaming between companies and governments will continue.

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WHY IT IS DIFFICULT FOR EUROPEAN TO UNDERSTAND THE CHINESE MARKET ACCESS PROCESS?

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OBJECTIVES: China is the third largest pharmaceutical market in the world. The aim of this study was to describe Chinese reimbursement process, assess current policies and provide the authors'view of Europeans difficulties to understand the Chinese market access. **METHODS:** A review was done using the latest-released official documents published by January 2014, to collect information regarding Chinese health care reimbursement pathways with the perspective of market access. Information was analysed based on authors'expertise, summarising the general pathway, and comparing with European routine. **RESULTS:** Three stakeholders participate in Chinese market access process: Ministry of Health (MoH) (supporting introduction of new health care technologies), National Development and Reform Commission (referencing prices based on technical information), and Bureau of Human Resources and Social Security (representing budget holders; focusing on cost containment). Differences between Chinese process and European routine result in European hardly understanding Chinese market access process: 1>in China, key opinion leaders introduce the dossier whereas in Europe, companies introduce the dossier. 2>in China, completely new health care technologies need real life pilot studies (RLPS) pre-requisitely to address the feasibility and impact of introduction, whereas in Europe, RLPS studies are requested after a granted market access. 3>in China, reimbursements start from regional level as pilot in 3 regions before becoming national whereas in Europe they start from national before regional contact. 4>in China, the three stakeholders negotiate internally reimbursements, prices and access conditions, whereas in Europe, companies negotiate with payers. 5>Chinese MoH has an envelope for direct funding of health care technologies through procurement, whereas no comparable envelope held by similar stakeholders in Europe. **CONCLUSIONS:** Chinese market access is difficult for European to understand because of fundamental differences in the paradigm sustaining pricing and reimbursement (P&R). Clarifying the rational for the differences in paradigm is a prerequisite for European understanding of the P&R in China.

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DEVELOPING A PATIENT CENTERED MODEL FOR CLINICIANS TO INDIVIDUALISE COST EFFECTIVE TREATMENT

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OBJECTIVES: The objective of this study was to develop a patient centred model which can be used by clinicians for each patient. **METHODS:** Two hypothetical, but realistic, treatments were selected to demonstrate the value of this model, a "modern atypical drug" and a "typical drug". The "modern atypical drug" is more expensive, results in faster return to work, less days in hospital and fewer repeat visits than the "typical drug". The computer based model provides default differences on all of these variables, however, the end user can over write these to allow the cost off-sets to be individualised to each patient they are treating. **RESULTS:** While the "modern atypical drug" is more expensive on a per day basis (\$4.00 vs \$0.30), days of treatment can be shorter, hospital stay and doctor visits reduced and days off work lower, making it a less expensive treatment option overall. In the base case, the medication cost of the "modern atypical drug" was \$108 more expensive over the year of treatment (\$4 per day x 30 days versus \$0.30 per day x 40 days). Shorter length of stay (3 versus 10 days at \$50 per day) resulted in \$350 in savings. Modest savings were gained from fewer doctor visits. Substantial savings would be expected from fewer days off work (14 versus 45 days off work at \$100 per day) with around \$3,100 saved. Overall savings were \$3,432. This model could be adjusted to reflect the expected outcome for each patient. **CONCLUSIONS:** This exercise demonstrates a novel model design which allows doctors to assess individual patients to determine whether or not they should be considered for more expensive treatments. It is well suited to health care environments in the region.

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WHAT ARE THE KEY DRIVING FACTORS BEHIND RSA DECISIONS IN AUSTRALIA?

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OBJECTIVES: Risk sharing agreements (RSA) are sometimes used to offset the risk associated with any uncertainties which may surround a drug at the time of launch. They can offer payers and manufacturers the flexibility to manage some of the perceived risks associated with, but not limited to, high therapy costs, discretionary use within an unapproved patient population, or lack of data at the time of product assessment. Given the frequent implementation of RSAs in Australia, the aim of